IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

KILEY WOLFE,	:	
	:	
Plaintiff	:	**CIVIL ACTION NO. 07-0348**
	:	
v.	:	
	:	
MCNEIL-PPC INC.; MCNEIL CONSUMER & SPECIALTY PHARMACEUTICALS, a division of MCNEIL-PPC, INC.; MCNEIL CONSUMER HEALTHCARE, a division of MCNEIL-PPC, INC.; JOHNSON & JOHNSON, INC.; and JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT, LLC	:	
	:	
Defendants	:	

PLAINTIFF'S TRIAL BRIEF

I. INTRODUCTION

This is a strict liability and negligent failure to warn case in which Plaintiff Kiley Wolfe, when she was nine years-old in 1996, developed Stevens-Johnson Syndrome (SJS)[1] and Vanishing Bile Duct Syndrome (VBDS)[2] caused by over-the-counter (OTC) Children's Motrin. Children's Motrin is manufactured, marketed, and sold by the Defendants.[3] After taking the Children's Motrin to treat a headache and fever, Kiley Wolfe had a life-threatening reaction to the drug and was hospitalized for her SJS and VBDS. A year later, she had a liver transplant.

In 2006, approximately ten years after Kiley Wolfe took Children's Motrin, the FDA determined that the OTC ibuprofen warning was inadequate and required that all ibuprofen manufacturers, including the Defendants, strengthen the warnings to include reference to potentially life-threatening skin reactions from OTC non-steroidal anti-inflammatory drugs ("NSAIDs"), including Children's Motrin. Unfortunately, Plaintiff did not have the benefit of the new strengthened and enhanced warning that instructed consumers to stop use of the drug when symptoms of "rash," "skin redness" and "blisters" appeared. The Children's Motrin caused exactly those symptoms in Kiley, however, the label did not instruct Kiley Wolfe's mother to stop the administration of Children's Motrin. The information provided to Plaintiff in 1996 was insufficient to warn parents that Children's Motrin could cause a life-threatening reaction, like the one Kiley

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[1] Stevens-Johnson Syndrome ("SJS") is a life-threatening drug-induced cutaneous reaction which can "kill or severely disable previously healthy people." Roujeau, J., *Medication Use and the Risk of Stevens-Johnson Syndrome of Toxic Epidermal Necrolysis*, N.E. J. MED., 12/14/95 at 1600. In 1995, the *New England Journal of Medicine* reported that there was a 4.5 relative-risk association between propionic acids, including ibuprofen and Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis ("TEN"). *Id.* at 1603.

[2] Vanishing Bile Duct Syndrome is a "rare cause of prolonged cholestatic liver disease." Srivistava M, Perez-Atayde A., Jonas MM, *Drug-associated acute onset vanishing bile duct and Stevens-Johnson syndromes in a child*, GASTROENTEROLOGY, September, 1998 (Volume 115, Issue 3, Pages 743-746). The acute form is "usually drug related." *Id.* at p. 743. Antonio Perez-Atayde, M.D., Ph.D., a co-author of the above mentioned and the treating pathologist on Plaintiff's case, testified that VBDS refers to a condition where the intrahepatic bile ducts "disintegrate" or are "destroyed." Deposition of Antonio Perez-Atayde, M.D., Ph.D., 7/14/10 at p.14.

[3] Defendants McNeil-PPC, Inc., McNeil Consumer and Speciality Pharmaceuticals, McNeil Consumer Healthcare, Johnson & Johnson and Johnson & Johnson Pharmaceutical Research & Development, LLC are collectively referred to herein as "Defendants."

Wolfe experienced. For four days, Plaintiff's mother continued to give her daughter the Children's Motrin without the warnings alerting her to the dangers of the drug when she reviewed the label for guidance. There was nothing on the label to alert Plaintiff's mother that the Children's Motrin was actually making Kiley sicker.

II. FACTS

A. The Defendants' Knowledge of the Dangers of Ibuprofen

As early as 1978, the Defendants knew of the dangers of SJS and liver injury caused by ibuprofen.[4] In the early 1980s, the Defendants largely controlled the over-the-counter market of non-aspirin antipyretics through the sale of their brand name acetaminophen product, Tylenol. During that time, however, other drug manufacturers were attempting to gain approval of over-the-counter ibuprofen. The Defendants did not own an ibuprofen product to sell and filed a petition with the FDA opposing the application by their competitors to sell ibuprofen to adults over-the-counter.

Specifically, McNeil complained to the FDA that ibuprofen was not as safe as the FDA believed it to be, that the warnings were too general and did not adequately inform consumers of the specific adverse reactions that could result from taking ibuprofen. McNeil argued in their 1984 Petition that "[t]he labeling for OTC ibuprofen is **completely inadequate**." McNeil also claimed that "**deaths that have occurred with ibuprofen** are from therapeutic usage at recommended doses....Thus, the risk of **fatal adverse reaction from ibuprofen** is substantially greater that with acetaminophen at recommended doses."

As early as 1984, the Defendants understood the problem of inadequate warnings with OTC labeling of ibuprofen and stated to the FDA, "McNeil strongly believes that, in light of current labeling practices and requirements for OTC products, there is a substantial likelihood that consumers will be misled, in a manner directly affecting safety, by the lack of specific warnings in OTC ibuprofen labeling."

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[4] Sternlieb, P. et al., *Stevens-Johnson Syndrome Plus Toxic Hepatitis Due to Ibuprofen*, N.Y.S.J MED., July 1978, p. 1239.

At the same time the Defendants were opposing OTC ibuprofen, they were conducting an internal study on its safety. The Defendants' report found that ibuprofen was associated with liver injury as well as Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis.[5] McNeil knew as early as 1984, 12 years before Kiley Wolfe was injured, that "In patients that develop hepatotoxicity there is usually an increase in the aminotransferases....soon after therapy is started. The drug should be stopped if any of the aminotransferases exceed 3 times the upper limit of normal." In 1996, within the first year that Children's Motrin was available to children in OTC form and as McNeil predicted twelve years before, Plaintiff developed SJS and hepatotoxicity after taking Children's Motrin and her aminotransferases, i.e. liver enzymes, were approximately **twenty (20) times** the upper limit of normal.

B. The Defendants Conceal Evidence of Stevens-Johnson Syndrome in the Boston University Fever Study

Ultimately, McNeil, not to be left out of the massively profitable ibuprofen market, acquired the Motrin brand from Pharmacia & Upjohn. Despite the knowledge that their research showed years before, McNeil quickly sought to gain FDA approval to market OTC ibuprofen to children. To gain regulatory approval, McNeil commissioned a clinical study about the safety of ibuprofen at the Slone Epidemiology Center at Boston University School of Medicine called the Boston University Fever Study (BUFS). During that study, approximately 53,000 children were treated with ibuprofen and there were reports of two (2) cases of Stevens-Johnson Syndrome. Defendant McNeil has admitted receiving two reports of children with SJS during the BUFS. Yet, it hid these cases from the FDA. This concealment is confirmed in the 2006 FDA Response to the Citizen's Petition where it stated that there were "**no cases of SJS or TEN reported**" to it.

C. The Defendants Seek Approval For OTC Children's Motrin That Do Not Warn of the Risks

When it was first sold OTC in 1995, the packaging/warnings for Children's Motrin did not warn of

the risks associated with ibuprofen use. The labels/stickers on the bottle of Children's Motrin contains dosage information and the warning "IMPORTANT: ***See box for complete information*** and save for future use." The box, however, contains no references to any hepatic or dermatological reactions and/or Stevens-Johnson syndrome. The box warns, "IMPORTANT: Read all product information before using." The entire OTC label in place when Plaintiff was injured reads as follows:

WARNINGS
ASPIRIN SENSITIVE CHILDREN:
- **This product contains no aspirin but may cause a severe reaction in people allergic to aspirin.**
- **Do not use this product if your child has had an allergic reaction to aspirin such as asthma, swelling, shock or hives.**

CALL YOUR DOCTOR IF:
- Your child is under a doctor's care for any serious condition or is taking any other drug
- Your child has problems or serious side effects from taking fever reducers or pain relievers
- Your child does not get any relief within the first day or 24 hours of treatment for pain or fever gets worse.
- Redness or swelling is present in the painful area.
- Sore throat is severe and lasts for more than two days or occurs with fever, headache, rash, nausea or vomiting.
- Any new symptoms appear.

DO NOT USE
- With any other product that contains ibuprofen, aspirin, naproxen sodium or acetaminophen
- for more than three days for fever or pain unless directed by a doctor
- for stomach pain unless directed by a doctor
- if your child is hydrated (significant fluid loss) due to continued vomiting, diarrhea, or lack of fluid intake
- if imprinted plastic bottle wrap or imprinted foil seal is broken.

While the label/sticker indicates that McNeil was informing users of Children's Motrin that they were to see the box for "***complete information***," there is nothing contained on the OTC warnings as of July 1995 which remotely indicate the dangerous conditions/reactions that can occur from ibuprofen use or what to do when those symptoms appear. Though the customer is supposed to "see the box for complete information," it is completely silent about the risks of ibuprofen use and what to do when dangerous symptoms appear. The only reference to rash is the warning that a child is not to take the medicine if the child had "an allergic reaction to aspirin such as asthma, swelling, shock or hives." The only other reference

to rash is in the section where a doctor would be called where there is a "sore throat and lasts for more than two days and occurs with a fever, headache, rash, nausea or vomiting."

At the time that Mrs. Leland gave Kiley Wolfe Children's Motrin, there was no warning to stop use of the Children's Motrin when symptoms of a life-threatening illness appeared. The Children's Motrin warning was silent on what to do when a child showed symptoms of rash, blisters and skin reddening. A warning instructing parents to stop administering Children's Motrin in the face of such symptoms would not be provided by Defendants for another 10 years, and would be done after the FDA ordered Defendants to do so.

D. The Defendants Dispute that Ibuprofen Causes SJS or VBDS Despite Making Such Warnings on their Prescription and Foreign Labels

Today, the Defendants warn in their prescription label that Children's Motrin can cause Stevens-Johnson Syndrome which can result in hospitalization and even death. Additionally, the Defendants warn European consumers of the dangers of SJS from ibuprofen in their OTC labels. The Defendants' prescription label for Children's Motrin states that there is a probable causal relationship between ibuprofen use and "hepatitis, jaundice, abnormal liver function tests.... [and] **Stevens-Johnson syndrome**." Though the threat of liver failure and SJS is noted on the **prescription** label for Children's Motrin, and the ibuprofen labels of J&J foreign subsidiaries also warn consumers of the risks of severe skin reactions from taking ibuprofen, McNeil and J&J did not warn U.S. consumers of the serious risk of injury associated with ibuprofen use. In fact, here, the Defendants continue to maintain that there is no proof that ibuprofen causes SJS or VBDS.

E. The Food and Drug Administration Confirms That the 1996 Warning Was Inadequate

In 2005, in response to the Citizen's Petition, the FDA asked McNeil to change the label for OTC ibuprofen products, it agreed. Unfortunately, the 1996 warning failed to alert the public of the dangers of Stevens-Johnson Syndrome, and its symptoms. The heightened warnings instructing parents to stop use of Children's Motrin at the sign of "rash", "skin redness" and "blisters" were not in place when Plaintiff was

harmed. Had Kiley Wolfe's mother had the benefit of the stronger and enhanced OTC warnings, which were added nearly a decade later, the damage Kiley suffered from the SJS and VBDS could have been avoided.

III. DISCUSSION

A. The Defendants Are Strictly Liable For Failing to Warn of the Dangers of Children's Motrin

The evidence supports Plaintiff's strict liability claim under Restatement (Second) § 402A.[6] It is well-settled under Pennsylvania law that a product may be rendered "defective" because it lacks necessary warnings or instructions which the seller should have supplied. [7] A seller must provide warnings and instructions to inform the user or consumer of the possible risks and inherent limitations of the product.[8] Under Pennsylvania law strict liability attaches where the warnings fail to inform the user of the risks inherent with the product.[9]

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[6] Restatement (Second) of Tort § 402A provides:

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

(a) the seller is engaged in the business of selling such a product, and

(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although

(a) the seller has exercised all possible care in the preparation and sale of his product, and

(b) the user or consumer has not brought the product from or entered into any contractual relation with the seller.

Restatement (Second) of Torts, § 402A.

[7] *See Webb v. Zern*, 422 Pa. 424, 220 A.2d 853 (1966)(adopting the theory of strict liability with regard to defective products in Pennsylvania).

[8] *Azzarello v. Black Brothers Co., Inc.*, 480 Pa. 547, 391 A.2d 1020 (1978); *Berkebile v. Brantly Helicopter Corporation*, 462 Pa. 83, 337 A.2d 893 (1975)(a plurality opinion observing that under strict liability a "'defective condition' is not limited to defects in design or manufacture").

[9] Courts of this Commonwealth have remarked:

> If the product is defective absent such warnings, and the defect is a proximate cause of the plaintiff's injury, the seller is strictly liable without proof of negligence. . . . Where warnings or instructions are required to make a product non-defective, it is the duty of the manufacturer to provide such warnings in a form that will reach the ultimate consumer and inform of the risks and inherent limits of the product. The duty to provide a non-defective product is non-delegable. . . .

Harford Mut. Ins. Co. v. Moorhead, 396 Pa. Super. 234, 578 A.2d 492 (1990)(quoting *Berkebile*, 337 A.2d at 902-903 (citing RESTATEMENT (SECOND) OF TORTS § 402A, comment h)); *Mackowick v. Westinghouse Electric Corporation*, Pa. , 575 A.2d 100 (1990); *Sherk v. Daisy-Heddon, Etc.*, 498 Pa. 594, 450 A.2d 615 (1982); *Toth v.*

The Defendants' label failed to warn Kiley and her mother that if a rash or muscosal reaction developed, that Children's Motrin should be stopped immediately and medical care should be sought. Between the time she gave Kiley her first dose and her development of "blisters", Mrs. Leland "stud[ied] the box and the bottle just to see if there was anything on there that I should look for." The 1996 OTC label claimed that it contained "complete information," however, it did not contain any warning to stop use when a rash was present or signs of an allergic reaction was present.

B. The Defendants Are Liable to Plaintiff Under A Negligent Failure to Warn Theory

Many failure-to-warn claims arise under the theory of strict products liability, but the principles of a strict liability failure-to-warn claim are applicable to a failure-to-warn claim under a theory of negligence.[10] The Defendants' negligence stems from its failure to warn consumers of the risks of SJS from taking ibuprofen. The Defendants possessed evidence from their own clinical trial showing two outpatient instances of SJS. There is no evidence that the Defendants took any action in response to these instances. The United States Court of Appeals for the Third Circuit has noted that under to the Restatement (Second) of Torts § 402A (comment J) a user is entitled to an evidentiary presumption that a warning would have been read and heeded.[11] "This presumption assists the failure to warn plaintiff in satisfying his burden of showing proximate cause."[12] Pennsylvania courts have also applied the "heeding presumption" in negligent failure

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Economy Forms Corp., 391 Pa.Super. 383, 571 A.2d 420 (1990); *Walton v. Avco*, 383 Pa.Super. 518, 557 A.2d 372 (1989); *Ellis v. Chicago Bridge & Iron Co.*, 376 Pa.Super. 220, 545 A.2d 906 (1988); *Carrecter v. Colson Equipment Co.*, 346 Pa.Super. 95, 499 A.2d 326 (1985); *Fravel v. Suzuki Motor Co. Ltd.*, 337 Pa.Super. 97, 486 A.2d 498 (1984); *Dambacher by Dambacher v. Mallis*, 336 Pa.Super. 22, 485 A.2d 408 (1984); *Pegg v. General Motors Corp.*, 258 Pa.Super 59, 391 A.2d 1074 (1978); *Snyder v. City of Philadelphia*, 129 Pa.Cmwlth. 89, 564 A.2d 1036 (1989).

[10] *See Shouey*, 49 F. Supp. 2d at 420 n. 3 (citing *Baldino v. Castagna*, 505 Pa. 239, 478 A.2d 807 (Pa. 1984)).

[11] *Pavlik v. Lane Limited/Tobacco Exporters International*, 135 F.3d 876, 883 (3d Cir. 1998).

[12] *Id.* (citation omitted).

to warn cases as well as those proceeding under a strict products liability theory.[13] Under Pennsylvania law, a person who supplies a chattel to another may be liable under a negligence theory for physical harm caused by the use of the chattel if the supplier:

> (1) knows or has reason to know that the chattel is in a dangerous condition;
> (2) has no reason to believe that those for whose use the chattel is supplied will realize the dangerous condition; and
> (3) **fails to warn those for whose use the chattel is supplied of the dangerous condition**.[14]

C. The Evidence Confirms that Ibuprofen Caused Kiley Wolfe's SJS and VBDS

Two days after starting the Motrin, Kiley began to complain of itching eyes and decreased appetite. On June 1, 1996, Kiley developed severe conjunctivitis, disseminated rash and huge blisters on the pinna of her ears. Kiley was rushed to the emergency room at Children's Hospital in Boston Children's Hospital Boston, where she was given additional ibuprofen.

At the time of admission, Kiley had a rash and was noted to have jaundice. Her liver function tests were more than twenty times the upper limit of normal. Her disease was felt to be meet the "criteria for Stevens-Johnson Syndrome." Consultation with the ophthalmology, dermatology and rheumatology services confirmed the diagnosis of Stevens-Johnson Syndrome. A thorough search for viral or biological etiology failed to reveal evidence of any candidate viruses or bacteria including Hepatitis A, Hepatitis B, Hepatitis C, Cytomeglovirus, Epstein-Barr Virus, Parvovirus B-19, Herpes Virus human Herpes 6, Herpes 2 Virus, Adenovirus, Mycoplasma, Leptospirosis, HIV, strep, salmonella, shigella, areomonas, plesiomonias, yersinia, e-coli, and campylobacteria. On June 3, 1996, the dermatologist and rheumatologist both suggested discontinuing NSAIDs, including ibuprofen. Her dermatologist noted, "SJS is usually secondary to drug and would d/c ibuprofen." The ibuprofen was discontinued.

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[13] *Shouey, by & Through Litz v. Duck Head Apparel Co.*, 49 F. Supp. 2d 413, 420 (M.D. Pa. 1999)(holding that a plaintiff need not produce evidence that a warning would have been heeded in order to survive the motion for summary judgment").

[14] *Overbeck v. Cates*, 700 A.2d 970, 972 (Pa. Super. 1997)(quoting Restatement (Second) of Torts, § 388)(Emphasis added).

Over the next few days, following the cessation of ibuprofen therapy, the rash, mucosal involvement and the pancreatitis all resolved. She underwent percutaneous liver biopsy on July 9, 1996, the results of which showed moderately severe cholestasis, mild portal fibrosis consisting of immature collagen, and striking damage and loss of the interlobular bile ducts, consistent with Vanishing Bile Duct Syndrome.[15] A July 9, 1996 liver biopsy was performed and the surgical pathology note states, "The clinico-pathological correlation suggest **drug toxicity**." Maureen Jonas, M.D., plaintiff's treating gastroenterologist and co-author of the *Gastroenterology* article testified, "**I believe if she hadn't had ibuprofen, she may not have had that liver damage, yes**."[16]

Her testimony confirms the diagnosis that Plaintiff's liver injury pointed to the only drug she was taking at the time, Children's Motrin**.**

Q. Okay. So would you say that it was more likely that it was the result of the ingestion of ibuprofen from your evaluation?
MS JONES: Object to the form.
A. More likely than?
Q. Than not.
A. Than not?
Q. Yeah.
A. I think if she hadn't taken ibuprofen, we would not have seen those signs and symptoms.
Q. Okay. Every other cause that you attempted to rule out, you ruled out?
A. Yes. We tried to rule out everything else.

* * * *

Q. And were you, as part of your differential and work up, able to rule out other causes which led you to the conclusion relating to the ibuprofen?
A. To the best of our ability, yes.[17]

Plaintiff ultimately had a liver transplant in Ohio in 1997. On August 24, 2006, William Balistreri, M.D., the pediatric hepatologist who coordinated Plaintiff's medical care before and after her liver transplant wrote a letter to William Wolfe, Plaintiff's father which reads, "In our opinion, Motrin was the direct cause

[15] *See* Mauren Jonas Dep., 4/8/10 at pp. 158-163. Maureen Jonas, M.D. testified, "my opinion was that there was an association with Motrin or ibuprofen, and that is why we wrote the article." *Id.*

[16] *Id.* at pp. 158-163.

[17] *Id.* at pp. 165.

of Stevens-Johnson Syndrome, resulting in liver failure and leading to a liver transplant." During his deposition, Dr. Balistreri was questioned by the Defendants' lawyers as follows:

> Q. Okay. This letter says, among other things, "In our opinion, Motrin was the direct cause of Stevens-Johnson Syndrome, resulting in liver failure and leading to a liver transplant." Is that something you believed as of August 24, 2006?
> A. Yes.
> Q. Okay. So it was your belief then that the Stevens-Johnson Syndrome caused the liver failure; is that accurate?
> A. That's correct.
> Q. Okay. And that the Motrin caused the Stevens Johnson Syndrome?
> A. Yes.
> Q. Okay. Has that belief changed in any way since August 24, 2006?
> A. No.[18]

Plaintiff's current treating pediatric hepatologist further confirmed the conclusion that Plaintiff's SJS and VBDS was caused by ibuprofen during his deposition.

> Q. Okay. And from your evaluation was there any other cause that you were able to identify of her vanishing bile duct syndrome other than her Stevens Johnson?
> MR. PULLIAM: Lacks foundation.
> Q. I'm sorry, Doctor, I didn't hear you.
> A. No.[19]
>
> * * * *
>
> Q. Doctor, am I correct that you've not seen anything to suggest any other etiology for Kiley Wolfe's vanishing bile duct syndrome other than her Stevens-Johnson Syndrome?
> MR. PULLIAM: Asked and answered, lacks foundation.
> MR. SHULER: You may answer.
> A. Yes.
> Q. All right. And is it fair to say that you have not seen anything to suggest any other etiologies for Kiley's Wolfe's Stevens-Johnson Syndrome other than her ingestion of Ibuprofen?
> MR. PULLIAM: Objection, lacks foundation, calls for speculation, asked and answered.
> A. Yes.[20]

[18] William Balistreri, M.D. Dep., 1/25/10 at pp. 20-21.

[19] *Id*. at p. 47.

[20] *Id*. at p 50.

Dr. Balistreri concurred with Plaintiff's treating physician at Children's Hospital in Boston that the SJS contributed to Plaintiff's injuries.

> Q. And in this case we have a liver biopsy that we've referred to and previously marked as Exhibit 15, correct?
> A. Yes.
> Q. Okay. And that suggests the cause of Kiley Wolfe's liver injury as drug toxicity; is that correct?
> MR. PULLIAM: Objection, leading.
> A. That's correct.
> Q. Okay. And in addition to that, Doctor, you've reviewed previously and had the chance to re-review some of the records from here at Cincinnati Children's Hospital as well as Boston Children's Hospital, those records from a clinical perspective in conjunction with that pathology report of liver biopsy suggest the cause of her liver injury to a drug-related toxicity; is that correct?
> MR. PULLIAM: Objection, leading.
> A. That's correct.
> Q. And, in fact, that's one of the things you referenced in the letter that you wrote in 2006 that Mr. Pulliam asked you about earlier, correct?
> MR. PULLIAM: Objection, leading, misstates the evidence.
> A. You're referring to the letter of August 24th?
> Q. Yes.
> A. Yes.
> Q. Okay. And, specifically, you make reference to the drug Motrin as the drug which resulted in the toxicity to the liver in that letter, correct?
> MR. PULLIAM: Objection, best evidence.
> A. My statement is that Motrin was the direct cause of Stevens-Johnson Syndrome resulting in liver failure and leading to a liver transplant.[21]

D. Plaintiffs Are Entitled to Punitive Damages

Plaintiff will prove that she is entitled to punitive damages under Maine law, which requires the showing that the defendant acted with "malice."[22] The Supreme Court of Maine upheld the right of a Plaintiff to recover an award of punitive damages and found that "[p]unitive damages will also be available, however, where deliberate conduct by the defendant, although motivated by something other than ill will

[21] *Id.* at p. 81-83.

[22] *Tuttle v. Raymond*, 494 A.2d. 1353, 1361 (Me. 1985).

toward a particular person, is so **outrageous** that malice toward a person injured as a result of that conduct can be implied."[23]

Under the holding in *Tuttle*, the conduct of the Defendants in ignoring the know risks associated with ibuprofen and then marketing the drug to American children meets the threshold of showing that the conduct is "so outrageous" for finding an award of punitive damages. McNeil hid from the FDA the two instances of SJS from the BUFS and did nothing in response to a incidence of liver failure in the year preceding plaintiff's injury. The Defendants have known since 1984 of the risks associated with ibuprofen use and did nothing to warn the public about it in their OTC warnings. The Defendants have also recognized the risk associated with ibuprofen was significant enough to warn about them in their prescription labeling and in the European OTC labels but did nothing for American children who used the same product. The decisions to withhold significant information about the dangers of a drug for constitutes outrageous action forming the basis of a punitive claim against the Defendants.

Respectfully submitted,

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[23] *Tuttle*, 494 A.2d at 1361. (Emphasis added).

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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

KILEY WOLFE,	:	CIVIL ACTION NO: 07-348
	:	
Plaintiff,	:	
	:	Judge: Jan E. DuBois
vs.	:	
	:	
McNEIL-PPC, INC., ET AL.	:	
	:	
Defendants.	:	

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CERTIFICATE OF SERVICE

I, **Thomas N. Sweeney, Esquire**, do hereby certify that on this day I caused a copy of the within Plaintiff's Trial Brief to be served, via U.S. First Class Mail on the following counsel:

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Dated: August 22, 2011